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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR          | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|-----------------|-------------|-------------------------------|----------------------|------------------|
| 10/820,543      | 04/08/2004  | Deshitha Airawana Edirisuriya | 1171/40711A/127A-CIP | 8375             |

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| EXAMINER |
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WOLLSCHLAGER, JEFFREY MICHAEL

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| ART UNIT | PAPER NUMBER |
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1791

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

06/16/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptodocket@trexlaw.com

|                              |   |   |  |
|------------------------------|---|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/820,543    | <b>Applicant(s)</b><br>EDIRISURIYA ET AL. |  |
|                              | <b>Examiner</b><br>JEFFREY WOLLSCHLAGER | <b>Art Unit</b><br>1791                   |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6, 12, 15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 12, 15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendment to the claims filed March 22, 2010 has been entered. Claims 6 and 20 are currently amended. Claims 6, 12, 15 and 17-22 are pending and under examination. Applicant's amendment to the claims and the arguments have overcome the previous 35 USC 112, first and second paragraph rejections as well as the objection to the specification.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 12, 15 and 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6 and 20 recite that the respiratory conduit is "adapted for use in a medical apparatus". In view of the arguments, the limiting effect of the recitation is unclear. Also see MPEP 2111.04. Applicant's arguments point to a specific citation from a reference cited in the disclosure (i.e. US 3,963,856). It is unclear to what extent the arguments are intended to limit the scope of the claims. Further, from the disclosure (paragraph [0031] of the published application), it is unclear whether the disclosed "medical apparatus" is the same as the disclosed "ventilation system therapy" (noting the use of the word "or" between the terms). Thus, it is also unclear whether the medical apparatus is required to be a ventilation system apparatus. It is unclear what requirements (i.e. physical properties of the conduit), if any, beyond those set forth in the combination of references below are required for the conduit to be reasonably considered "adapted for use in a medical apparatus". To the extent the phrase is understood to limit the claims, the examiner submits that the combination is "adapted

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for use in a medical apparatus". Claims 12, 15, 17-19, 21 and 22 are rejected as dependent claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 12, 15, and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godeau (US 5,749,995) in view of Uchiyama et al. (US 6,334,615).

Regarding claim 6, Godeau teaches a method of producing a watertight coupling between a tube and an endpiece comprising providing a tube (10) made of plastic or elastomer (col. 3, lines 52-54) (i.e. a flexible conduit); injection molding an elastomer/soft rubber onto the conduit adjacent to the end of the conduit to form an annular portion (16)/cuff (Figure 8; col. 5, lines 51-55; col. 6, lines 1-11; claims 3 and 4); and subsequently injection molding a plastic, such as polyamide, over the annular portion (16)/cuff to form a ring (13)/connector (Figure 9; col. 5, lines 15-18), wherein the annular portion (16)/cuff shields the tube (10)/conduit from

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injected plastic to prevent damage to the tube/conduit (Figure 1 and Figure 9). Godeau does not teach the plastic is injected at a higher temperature than the melting point of the rubber/elastomer. However, Uchiyama et al. teach an injection molding process wherein a flexible resin (e.g. an elastomer, col. 4, line 43) and a rigid resin (e.g. a polyamide, col. 3, line 55) are separately injected and wherein the rigid resin is injected at a higher temperature than the melting point of the flexible resin in order to melt the flexible resin at the interface and form a unitary body having a strong fusion bond between the two materials (Figure 22; col. 3, lines 41-50; col. 4, lines 14-22; col. 5, lines 31-40).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Godeau and to have injected the plastic at a higher temperature than the melting point of the rubber/elastomer, as suggested by Uchiyama et al., for the purpose, as suggested by Uchiyama et al., of forming a strong bond between the two materials.

As to claim 12, Godeau employs an elastomer/rubber material for the annular portion (16)/cuff. As such, to the extent set forth in the claim, the material is understood to be deformable, relieve stress and generally permit movement relative to the connector.

As to claim 15, Godeau employs a polyamide, for example, as the ring (13)/connector portion. The ring (13)/connector is compatible with other parts (Figure 1).

As to claims 17, Uchiyama et al. teach the rigid resin has a melting point higher than the melting point of the flexible resin and inject the rigid resin at a temperature sufficient to cause the cuff to melt at the interface (Figure 22; col. 3, lines 41-50; col. 4, lines 14-22; col. 5, lines 31-40). It would have been obvious to one having ordinary skill to have employed resins having the melting temperature relationship as claimed for the same reasons set forth above in the rejection of claim 6.

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As to claim 18, Godeau teach the connector/ring is molded over the cuff/annular portion toward the end of the conduit and the cuff/annular ring extends out of an inner end of the connector away from the end of the conduit (Figure 1 and Figure 12).

As to claim 19, the cuff/annular portion of Godeau prevents contact between the plastic and the tube/conduit behind the cuff/annular portion (Figure 1).

Regarding claim 20, Godeau teaches a method of producing a watertight coupling between a tube and an endpiece comprising providing a tube (10) made of plastic or elastomer (col. 3, lines 52-54) (i.e. a flexible conduit); injection molding an elastomer/soft rubber onto the conduit adjacent to the end of the conduit to form an annular portion (16)/cuff (Figure 8; col. 5, lines 51-55; col. 6, lines 1-11; claims 3 and 4); and subsequently injection molding a plastic, such as polyamide, over the annular portion (16)/cuff to form a ring (13)/connector (Figure 9; col. 5, lines 15-18), wherein the annular portion (16)/cuff insulates and prevents contact between tube (10)/conduit and the molten plastic where the annular portion (16)/cuff is located (Figure 1). Godeau does not teach the plastic is injected at a higher temperature than the melting point of the rubber/elastomer. However, Uchiyama et al. teach an injection molding process wherein a flexible resin (e.g. an elastomer, col. 4, line 43) and a rigid resin (e.g. a polyamide, col. 3, line 55) are separately injected and wherein the rigid resin is injected at a higher temperature than the melting point of the flexible resin in order to melt the flexible resin at the interface and form a unitary body having a strong fusion bond between the two materials (Figure 22; col. 3, lines 41-50; col. 4, lines 14-22; col. 5, lines 31-40).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Godeau and to have injected the plastic at a higher temperature than the melting point of the rubber/elastomer, as suggested

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by Uchiyama et al., for the purpose, as suggested by Uchiyama et al., of forming a strong bond between the two materials.

As to claim 21, Godeau do not teach the claimed temperature relationship. However, Uchiyama et al. teach an injection molding process wherein a flexible resin (e.g. an elastomer, col. 4, line 43) and a rigid resin (e.g. a polyamide, col. 3, line 55) are separately injected and wherein the rigid resin is injected at a higher temperature than the melting point of the flexible resin in order to melt the flexible resin at the interface and form a unitary body having a strong fusion bond between the two materials. Additionally, Uchiyama et al. teach the rigid resin has a melting point higher than the melting point of the flexible resin and inject the rigid resin at a temperature sufficient to cause the cuff to melt (Figure 22; col. 3, lines 41-50; col. 4, lines 14-22; col. 5, lines 31-40).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Godeau and to have injected the rubber/elastomer and the plastic layers at temperatures corresponding to their melt temperatures such that the cuff is injected at a lower temperature than the connector, as suggested by Uchiyama et al., for the purpose, as suggested by Uchiyama et al., of forming a strong bond between the two materials and for the additional purposes of saving energy by avoiding overheating the resins and avoiding unnecessary heat history/degradation of the resins.

As to claim 22, Godeau employs an elastomer/rubber material for the annular portion (16)/cuff. As such, to the extent set forth in the claim, the material is understood to be deformable, relieve stress and generally permit cushioning.

### ***Response to Arguments***

Applicant's arguments filed March 22, 2010 have been fully considered, but they are not persuasive. Applicant argues that Godeau does not experience the same problem that the claimed invention solves and would therefore not be motivated to modify the method of Godeau. Further, applicant argues that Uchiyama is taken out of context and that the different article being formed by Uchiyama would have no obvious application to the claimed method. This argument is not persuasive. The examiner submits that the combination is proper and that one having ordinary skill in the plastic molding arts (i.e. the analogous nature of the applied references) would find the teaching of Uchiyama regarding the specific molding temperatures of the plastic/rubber materials, which are similar to the materials molded by Godeau, applicable. Further, while the reason for combining the references (i.e. forming a strengthened bond between the materials) may be different than applicant's (i.e. avoiding damage to the underlying conduit), this alone can not be the basis for patentability when the combination teaches and suggests all of the claimed process steps. In other words, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO



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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY WOLLSCHLAGER whose telephone number is (571)272-8937. The examiner can normally be reached on Monday - Thursday 6:45 - 4:15, alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeff Wollschlager/  
Primary Examiner  
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June 14, 2010

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